

**JULY 2025** 

<b>Update Summary</b>			
Update Existing Test	7/21/2025	AABG - "Amoeba (E histolytica) Ab, IgG"	
Update Existing Test	7/21/2025	ACPT - "Acid Phosphatase, Total, Serum"	
Update Existing Test	7/1/2025	ADDS - "DNA (ds) Antibody"	
Update Existing Test	7/7/2025	AHPR - "Acute Hepatitis Panel"	
Update Existing Test	7/21/2025	ASAFB - "Antimicrobial Susceptibility, AFB/Mycobacteria"	
Update Existing Test	7/21/2025	ASHKE - "Ashkenazi Jewish Mutation"	
Update Existing Test	7/21/2025	BILAT - "Bile Acids, Total"	
Update Existing Test	7/21/2025	BIS - " Bismuth, Whole Blood"	
Update Existing Test	7/8/2025	BRCAP - "BRCA Panel (BRCA1, BRCA2)"	
Update Existing Test	7/21/2025	CADEP - "Cadmium Exposure Panel-OSHA"	
Update Existing Test	7/8/2025	CIFAS - "Cutaneous Immfluor. Ab, IgG/IgG4, S"	
Update Existing Test	7/21/2025	COBLD - " Cobalt, Whole Blood"	
Update Existing Test	7/21/2025	COBS - "Cobalt, Serum"	
Update Existing Test	7/21/2025	ECHIG - "Echinococcus Antibody IgG"	
Update Existing Test	8/4/2025	GHBSP - "Gamma-Hydroxybutyric Acid (GHB) with Reflex to	
		Confirm, Ser"	
Update Existing Test	7/7/2025	5 HAAB - "Hepatitis A Antibody, Total"	
Update Existing Test	7/7/2025	HAM - "Hepatitis A Antibody, IgM"	
Update Existing Test	7/7/2025	HBCAB - "Hepatitis B Core Antibody, Total"	
Update Existing Test	7/7/2025	HBCM - "Hepatitis B Core Antibody, IgM"	
Update Existing Test	7/7/2025	HBSAB - "Hepatitis B Surface Antibody"	
Update Existing Test	7/7/2025	HBSAG - "Hepatitis B Surface Antigen"	
Update Existing Test	7/7/2025	HBVSC - "Hepatitis B Screening Panel"	
Update Existing Test	7/7/2025	HCVR - "Hepatitis C Antibody, Diagnostic, with reflex to PCR"	
Update Existing Test	7/7/2025	HCVSR - "Hepatitis C Antibody, Screening, with reflex to PCR"	
Update Existing Test	7/1/2025	HPEP - "Hypersensitivity Pneumonitis Extended Panel"	
Update Existing Test	7/8/2025	<u>LPA - "Lipoprotein LP(a)"</u>	
Update Existing Test	7/21/2025	NMETD - "N-methyl-D-Aspartate Rcptr Ab, IgG, Ser"	
Update Existing Test	7/28/2025	NTELU - "Collagen Cross Linked N Telopeptide (NTx), 24H U"	
Update Existing Test	7/28/2025	NTXUR - "Collagen Cross Linked N Telopeptide, Urine"	
Update Existing Test	7/21/2025	PBINP - " Lead, Industrial, Whole Blood"	
Update Existing Test	7/21/2025	PHGAM - "Phosphatidylserine Antibodies, IgG, IgM, and IgA"	
Update Existing Test	7/8/2025	UMERA - " Mercury, 24 Hour Urine"	
Update Existing Test	7/21/2025	ZNIC - "Nickel"	
Inactivate Test With Replacement	7/21/2025	DPYDV - "Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants"	
		replaced by DPYDA - "Dihydropyrimidine Dehydrogenase (DPYD)"	

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**JULY 2025** 

Inactivate Test With Replacement	7/1/2025	MAGAB - "MAG Autoantibody" replaced by MAGME - "Myelin- Associated Glycoprotein (MAG) Ab, IgM, EIA"	
Inactivate Test With Replacement	7/29/2025	PBKQL - "BK Virus DNA PCR, Qualitative, Plasma" replaced by BKQLP - "BK Virus DNA PCR, Qualitative, Plasma"	
Inactivate Test With Replacement	7/29/2025	PBKQN - "BK Virus DNA PCR, Quantitative, Plasma" replaced by BKQNP - "BK Virus DNA PCR, Quantitative, Plasma"	
Inactivate Test With Replacement	7/29/2025	RBMA - "Renal Pathology Consultation" replaced by RPCWT - "Renal Pathology Consultation, Wet Tissue"	
Inactivate Test With Replacement	7/29/2025	TESF - "Free Testosterone" replaced by TESB - "Testosterone, Free, Bioavailable and Total, MS"	
Inactivate Test With Replacement	7/29/2025	<u>UBKQL - "BK Virus DNA PCR, Qualitative, Urine" replaced by BKQLU - "BK Virus DNA PCR, Qualitative, Urine"</u>	
Inactivate Test With Replacement	7/29/2025	UBKQN - "BK Virus DNA PCR, Quantitative, Urine" replaced by BKQNU - "BK Virus DNA PCR, Quantitative, Urine"	
Inactivate Test Without Replacement	7/21/2025	B27A - "HLA B-27 Genotyping (Confirmation)"	
Inactivate Test Without Replacement	7/21/2025	LACPL - "Lactic Acid, Plasma"	
Inactivate Test Without Replacement	7/21/2025	TPRHH - "ThinPrep with reflex to HPV High Risk E6/E7"	

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**JULY 2025** 

Update Existing Test				
Effective Date	7/21/2025			
Name	Amoeba (E histolytica) Ab, IgG			
Code	AABG			
Interface Order Code	3680600			
Legacy Code	AABAR			
Notes	Update to performed days and turnaround time.			
Required Testing Changes				
Performed Days	Tuesday			
Turnaround Time	3 - 11 days			

Update Existing Test			
Effective Date	7/21/2025		
Name	Acid Phosphatase, Total, Serum		
Code	ACPT		
Interface Order Code	3680050		
Legacy Code	ACPTARP		
Notes	Update to alternate specimen.		
Required Testing Changes			
Alternate Specimen	Serum separator tube (SST)		

Update Existing Test				
Effective Date	7/1/2025			
Name	DNA (ds) Antibody			
Code	ADDS			
Interface Order Code	3000200			
Legacy Code	ADDS			
Notes	Update to alternate specimen.			
Required Testing Changes				
Alternate Specimen	Plasma: Lavender EDTA			

Update Existing Test				
Effective Date	7/7/2025			
Name	Acute Hepatitis Panel			
Code	AHPR			
Interface Order Code	3001485			
Legacy Code	AHPR			
Notes	Update to performed days and turnaround time.			
Required Testing Changes				
Performed Days	Monday - Friday			
Turnaround Time	5 days			

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**JULY 2025** 

Update Existing Test			
Effective Date	7/21/2025		
Name	Antimicrobial Susceptibility, AFB/Mycobacteria		
Code	ASAFB		
Interface Order Code	3600499		
Legacy Code	ASAFB		
Notes	Update to specimen requirements, rejection criteria, stability, and methodology.		
Required Testing C	hanges		
Specimen Required	Collect: Actively growing isolate in pure culture.  Specimen Preparation: Transport sealed container with pure isolate on solid or liquid media.  Place each isolate in an individually sealed bag.  Transport Temperature: Room temperature		
Rejection Criteria	Mixed isolates or non-viable organisms. M. tuberculosis complex isolates submitted on an agar plate.		
Stability	Room temperature: 2 weeks Refrigerated: 2 weeks Frozen: Unacceptable		
Methodology	Broth Macrodilution/Broth microdilution		

Update Existing Test				
Effective Date	7/21/2025			
Name	Ashkenazi Jewish Mutation			
Code	ASHKE			
Interface Order Code	3515020			
Legacy Code	ASHKEN			
Notes	Update to specimen requirements, alternate specimen, stability, methodology, and turnaround			
Notes	time.			
Required Testing Cl	nanges			
	Collect: Lavender EDTA			
Specimen Beguired	Specimen Preparation: Send 3.0 mL whole blood in a screw capped plastic vial.			
Specimen Required	Minimum Volume: 1.0 mL			
	Transport Temperature: Refrigerated			
Alternate Specimen	Yellow ACD solution A or B, Pink K2 EDTA			
	Room temperature: 72 hours			
Stability	Refrigerated: 7 days			
	Frozen: 30 days			
Methodology	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring			
Turnaround Time	7 - 12 days			

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**JULY 2025** 

Update Existing Test				
Effective Date	7/21/2025			
Name	Bile Acids, Total			
Code	BILAT			
Interface Order Code	3600347			
Legacy Code	BILAT			
Notes	Update to stability.			
Required Testing Changes				
Stability	After separation from cells:  Room temperature: 24 hours  Refrigerated: 14 days  Frozen: 3 months			

Update Existing Test				
Effective Date	7/21/2025			
Name	Bismuth			
Code	BIS			
Interface Order Code	3500563			
Legacy Code	BIS			
Notes	Update to test name and result component name.			
Required Testing Changes				
Name	Bismuth, Whole Blood			
Result Code	Name	LOINC Code	AOE/Prompt	
3500563	Bismuth, Whole Blood	8161-2	No	

Update Existing Test			
Effective Date	7/8/2025		
Name	BRCA Panel (BRCA1, BRCA2)		
Code	BRCAP		
Interface Order Code	3400510		
Legacy Code	BRCAP		
Notes	Update to turnaround time.		
Required Testing Changes			
Turnaround Time	Turnaround Time 14 - 21 days from completed pre-authorization		

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**JULY 2025** 

Update Existing Test				
Effective Date		7/21/2025		
Name	Cadmiu	m Exposure Panel-OS	SHA	
Code		CADEP		
Interface Order Code		3687700		
Legacy Code	CADEXP			
Notes	Update to result component name.			
Required Testing C	hanges			
Result Code	Name	LOINC Code	AOE/Prompt	
3687710	Creatinine, Urine - per volume	2161-8	No	
3687720	Cadmium, Urine - ratio to CRT	13471-8	No	
3687730	Cadmium, Urine - per volume 5611-9 No			
3687740	Beta 2 Microglobulin, ratio to CRT 13485-8 No			
3687750	pH, Urine	2756-5	No	
3687760	Beta 2 Microglobulin, Urine	1953-9	No	
3687770	Cadmium, Whole Blood	5609-3	No	

Update Existing Test		
Effective Date	7/8/2025	
Name	Cutaneous Immfluor. Ab, IgG/IgG4, S	
Code	CIFAS	
Interface Order Code	3800413	
Legacy Code	CIFAS	
Notes	Update to CPT codes.	
Required Testing Changes		
CPT Code(s)	88346, 88350, plus 88350 if reflexed to titer	

Update Existing Test			
Effective Date	7/21/2025		
Name	Cobalt - Blood		
Code	COBLD		
Interface Order Code	3619940		
Legacy Code	COBBARP		
Notes	Update to test name, result component name, and reference range.		
Required Testing Changes			
Name	Cobalt, Whole Blood		
Reference Range	Less than or equal to 3.9 ug/L		
Result Code	Name	LOINC Code	AOE/Prompt
3619940	Cobalt, Whole Blood	5625-9	No

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**JULY 2025** 

The data of the table		
<b>Update Existing</b>	g Test	
Effective Date	7/21/2025	
Name	Cobalt, Serum	
Code	COBS	
Interface Order Code	3689080	
Legacy Code	COBSARP	
Notes	Update to specimen requirements and alternate specimen.	
Required Testing C	hanges	
Specimen Required	Patient Preparation: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals and nonessential over-the-counter medications (upon the advice of their physician). Collect: Dark blue trace element no additive  Specimen Preparation: Centrifuge and separate serum from cells within 2 hours of collection.  Send 2.0 mL serum room temperature in a blue capped ARUP metal-free screw capped plastic vial. Please contact laboratory for metal-free screw capped plastic vials. Specimens in other containers will be rejected. Do not use utensils (i.e., syringes, needles, or pipettes) in the collection or transfer of the sample, pour directly into transport tube.  Minimum Volume: 0.5 mL  Transport Temperature: Room temperature	
Alternate Specimen	Plasma: Dark blue trace element (K2EDTA), Dark blue sodium heparin	

<b>Update Existing</b>	g Test	
Effective Date	7/21/2025	
Name	Echinococcus Antibody IgG	
Code	ECHIG	
Interface Order Code	3620500	
Legacy Code	ECHINOCAR	
Notes	Update to rejection criteria, stability, methodology, reference range, performed days, and	
Notes	turnaround time.	
Required Testing Cl	nanges	
Rejection Criteria	Contaminated, heat-inactivated, grossly hemolyzed, or severely lipemic specimens	
	Room temperature: 48 hours	
Stability	Refrigerated: 14 days	
	Frozen: 1 month	
Methodology	Semi-quantitative Enzyme Linked Immunosorbent Assay (ELISA)	
Reference Range	0 - 8 U Negative	
Performed Days	Tuesday	
Turnaround Time	3 - 10 days	

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**JULY 2025** 

Update Existing Test		
Effective Date	8/4/2025	
Name	Gamma-Hydroxybutyric Acid (GHB) with Reflex to Confirm, Ser	
Code	GHBSP	
Interface Order Code	3300067	
Legacy Code	GHBSP	
Notes	Update to turnaround time.	
Required Testing Changes		
Turnaround Time	6 - 10 days (If positive: 8 - 15 days)	

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis A Antibody, Total	
Code	HAAB	
Interface Order Code	3000710	
Legacy Code	HAAB	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis A Antibody, IgM	
Code	HAM	
Interface Order Code	3010010	
Legacy Code	HAM	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis B Core Antibody, Total	
Code	НВСАВ	
Interface Order Code	3000680	
Legacy Code	НВСАВ	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

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**JULY 2025** 

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis B Core Antibody, IgM	
Code	HBCM	
Interface Order Code	3010200	
Legacy Code	НВСМ	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis B Surface Antibody	
Code	HBSAB	
Interface Order Code	3001640	
Legacy Code	HBSAB	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis B Surface Antigen	
Code	HBSAG	
Interface Order Code	3000660	
Legacy Code	HBSAG	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

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**JULY 2025** 

Update Existing Test		
Effective Date	7/7/2025	
Name	Hepatitis B Screening Panel	
Code	HBVSC	
Interface Order Code	3000530	
Legacy Code	HBVSC	
Notes	Update to performed days and turnaround time.	
Required Testing Changes		
Performed Days	Monday - Friday	
Turnaround Time	1 - 3 days	

Update Existing Test			
Effective Date	7/7/2025		
Name	Hepatitis C Antibody, Diagnostic, with reflex to PCR		
Code	HCVR		
Interface Order Code	3001440		
Legacy Code	HCVR		
Notes	Update to performed days and turnaround time.		
Required Testing Changes			
Performed Days	Monday - Friday		
Turnaround Time	5 days		

Update Existing Test			
Effective Date	7/7/2025		
Name	Hepatitis C Antibody, Screening, with reflex to PCR		
Code	HCVSR		
Interface Order Code	3001452		
Legacy Code	HCVSR		
Notes	Update to performed days and turnaround time.		
Required Testing Changes			
Performed Days	Monday - Friday		
Turnaround Time	5 days		

Update Existing Test		
Effective Date	7/1/2025	
Name	Hypersensitivity Pneumonitis Extended Panel	
Code	HPEP	
Interface Order Code	3600507	
Legacy Code	HPEP	
Notes	Update to CPT codes.	
Required Testing Changes		
CPT Code(s)	86003, 86005, 86606 x 5, 86606 x 5	

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**JULY 2025** 

Update Existing Test		
Effective Date	7/8/2025	
Name	Lipoprotein LP(a)	
Code	LPA	
Interface Order Code	3000408	
Legacy Code	LPA	
Notes	Update to New York approval and example report on website.	
Required Testing Changes		
New York Approval	New York Approval New York DOH Approval Status: Yes	

Update Existing Test			
Effective Date	7/21/2025		
Name	N-methyl-D-Aspartate Rcptr Ab, IgG, Ser		
Code	NMETD		
Interface Order Code	3600159		
Legacy Code	NMETD		
Notes	Update to alternate specimen and stability.		
Required Testing Changes			
Alternate Specimen	Red top		
	After separation of cells:		
Stability	Room temperature: 48 hours		
	Refrigerated: 14 days		
	Frozen: 1 year		

Update Existing Test			
Effective Date	7/28/2025		
Name	Collagen Cross Linked N Telopeptide (NTx), 24H U		
Code	NTELU		
Interface Order Code	3400922		
Legacy Code	NTELU		
Notes	Update to performed days and turnaround time.		
Required Testing Changes			
Performed Days	Monday - Saturday		
Turnaround Time	3 - 5 days		

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**JULY 2025** 

Update Existing Test			
Effective Date	7/28/2025		
Name	Collagen Cross Linked N Telopeptide, Urine		
Code	NTXUR		
Interface Order Code	3715700		
Legacy Code	NTXURSP		
Notes	Update to performed days and turnaround time.		
Required Testing Changes			
Performed Days	Monday - Saturday		
Turnaround Time	3 – 5 days		

Update Existing Test			
Effective Date	7/21/2025		
Name	Lead, Industrial Exposure Panel, Adults		
Code	PBINP		
Interface Order Code	3600489		
Legacy Code	PBINP		
Notes	Update to test name and reference range.		
Required Testing Changes			
Name	Lead, Industrial, Whole Blood		
Reference Range	Components	Reference Interval	
	Lead, Industrial, Whole Blood	Less than or equal to <b>3.4</b> μg/dL	
	Zinc Protoporphyrin, Blood	0-40 μg/dL	
	Zinc Protoporphyrin (ZPP) Whole Blood Ratio	0-69 μmol ZPP/mol heme	

Update Existing Test			
Effective Date	7/21/2025		
Name	Phosphatidylserine Antibodies, IgG, IgM, and IgA		
Code	PHGAM		
Interface Order Code	3703180		
Legacy Code	PHOSGMASP		
Notes	Update to performed days.		
Required Testing Changes			
Performed Days	Monday, Wednesday, Friday		

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**JULY 2025** 

Update Existing Test			
Effective Date	7/8/2025		
Name	Mercury Urine		
Code	UMERA		
Interface Order Code	3671570		
Legacy Code	UMERARP		
Notes	Update to test name.		
Required Testing Changes			
Name	Mercury, 24 Hour Urine		

Update Existing	g Test			
Effective Date	7/21/2025			
Name	Nickel			
Code	ZNIC			
Interface Order Code	3508030			
Legacy Code	NIC			
Notes	Update to specimen requirements.			
<b>Required Testing Cl</b>	quired Testing Changes			
Specimen Required	Patient Preparation: Diet, medication and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals and nonessential over-the-counter medications (upon advice of their physician). Collect: Dark blue trace element no additive.  Specimen Preparation: Centrifuge, separate serum from cells within 2 hours of collection and send 2.0 mL serum in a blue-capped ARUP metal-free screw capped plastic vial. Do not use utensils (i.e., syringes, needles, or pipettes) in the collection or transfer of the sample, pour directly into transport tube.  Minimum Volume: 0.5 mL  Transport Temperature: Refrigerated			

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**JULY 2025** 

In a still rate Took	Marile Development		
	With Replacement		
Effective Date	7/21/2025		
	Inactivated To	est	
Name	Dihydropyrimidine De	hydrogenase (DP)	/D), 3 Variants
Code		DPYDV	
Legacy Code		DPYDV	
Interface Order Code		3600414	
	Replacement 7	Гest	
Name	Dihydropyrimidi	ne Dehydrogenase	e (DPYD)
Code		DPYDA	
CPT Code(s)	81232		
Notes	New York DOH Approval Status: Yes		
Specimen Requiren	nents		
Specimen Required	Collect: Lavender EDTA Specimen Preparation: Send 3.0 mL whole blood. Minimum Volume: 1.0 mL Transport Temperature: Refrigerated		
Alternate Specimen	Whole blood: Yellow ACD A or B		
Rejection Criteria	Plasma or serum, heparinized specimens. Frozen specimens in glass collection tubes.		
Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen: 30 days		
<b>Performing Informa</b>	ation		
Methodology	Polymerase Chain React	on (PCR)/Fluoresc	ence Monitoring
Reference Range		See report	
Performed Days	Varies		
Turnaround Time	7 - 12 days		
Performing Laboratory	ARUP Reference Laboratory		
Interface Informati	on		
Legacy Code	DPYDA		
Interface Order Code	3600534		
Result Code	Name	LOINC Code	AOE/Prompt
3600416	DPYD Specimen	31208-2	No
3600536	DPYD Allele 1		No
3600537	DPYD Allele 2		No
3600418	DPYD Phenotype	104284-5	No
3600419	DPYD Interpretation	79719-1	No
3600421	EER Dihydropyrimidine Dehydrogenase	11526-1	No

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108

#### **EXAMPLE, REPORT W**

WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 06/18/2025 06:55 Received: 06/18/2025 06:55

**Test Name** Result Flag Ref-Ranges Units <u>Site</u>

#### Dihydropyrimidine Dehydrogenase (DPYD)

DPYD Specimen Whole Blood ARRL DPYD Allele 1 \*2A ARRL AB ARRL DPYD Allele 2 \*13 AB ARRI DPYD Phenotype **Poor** AB ARRL **DPYD** Interpretation See Note

This result has been reviewed and approved by Pinar Bayrak-Toydemir, M.D., Ph.D.

BACKGROUND INFORMATION: Dihydropyrimidine Dehydrogenase (DPYD)

CHARACTERISTICS: 5-fluorouracil (5-FU) is the most frequently used chemotherapeutic drug for the treatment of many types of cancer, particularly colorectal adenocarcinoma. Grade III-IV drug toxicity attributed to 5-FU occurs in approximately 16 percent of patients, and may include hematologic, gastrointestinal, and dermatologic complications. In some cases, this toxicity can cause death. When 5-FU is metabolized in the body, approximately 80 percent is catabolized by the dihydropyrimidine dehydrogenase (DPD) enzyme. Variants in the DPYD gene can lead to reduced 5-FU catabolism, resulting in the aforementioned toxicity complications. INHERITANCE: Autosomal codominant.

CAUSE: DPYD gene mutations.

DPYD Variants Tested:

(Variants are numbered according to NM 000110 transcript)

Nonfunctional alleles and increased toxicity risk:

c.1024G>A (rs183385770)

c.1774C>T (rs59086055)

\*13 (c.1679T>G, rs55886062)

\*2A (c.1905+1G>A, rs3918290)

Decreased function alleles and increased toxicity

risk:

c.557A>G (rs115232898)

c.868A>G (rs146356975)

c.2279C>T (rs112766203)

c.2846A>T (rs67376798)

c.1129-5923C>G (rs75017182)

Functional alleles and normal enzymatic activity: \*1 indicates no variants detected.

METHODOLOGY: Polymerase chain reaction (PCR) and

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H418000000 WX000003826 Printed D&T: 06/18/25 06:57 Ordered By: CLIENT CLIENT WX0000000002823



QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 36 Y

#### **Referral Testing**

Collected: 06/18/2025 06:55 Received: 06/18/2025 06:55

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

fluorescence monitoring.

ANALYTICAL SENSITIVITY and SPECIFICITY: Greater than 99 percent.

LIMITATIONS: Only the targeted DPYD variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. 5-FU drug metabolism, efficacy, and risk for toxicity may be affected by genetic and nongenetic factors that are not evaluated by this test. Genotyping does not replace the need for therapeutic drug monitoring or clinical observation.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

EER Dihydropyrimidine Dehydrogenase

See Note

ARRL

Performed By: ARUP Laboratories

500 Chipeta Way

Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

CLIA Number: 46D0523979

**Reported Date:** 06/18/2025 06:56 DPYDA

Performing Site:

ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H418000000 WX0000003826 Printed D&T: 06/18/25 06:57 Ordered By: CLIENT CLIENT WX000000000002823

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 2



**JULY 2025** 

	With Replacement		
Effective Date	7/1/2025		
Inactivated Test			
Name	MAG Autoantibody		
Code	MAGAB		
Legacy Code	MAGAAB		
Interface Order Code	3504670		
	Replacement Test		
Name	Myelin-Associated Glycoprotein (MAG) Ab, IgM, EIA		
Code	MAGME		
CPT Code(s)	83520		
Notes	New York DOH Approval Status: Yes		
Specimen Requiren	nents		
Specimen Required	Collect: Serum separator tube (SST)  Specimen Preparation: Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial.  Minimum Volume: 0.2 mL  Transport Temperature: Refrigerated (cold packs)		
Alternate Specimen	Serum: Red top		
Rejection Criteria	Sample received room temperature		
Stability	Room Temperature: 48 hours Refrigerated: 7 days Frozen: 30 days		
Performing Informa	ation		
Methodology	Enzyme Immunoassay		
Reference Range	Normal <1:1600 Moderately Elevated 1:1600-1:3200 Highly Elevated ≥1:6400		
Performed Days	Monday, Thursday		
Turnaround Time	5 - 9 days		
Performing Laboratory	Quest		
Interface Informati	on		
Legacy Code	MAGME		
Interface Order Code	3401069		
Result Code	Name LOINC Code AOE/Prompt		
3401069	Myelin-Associated Glycoprotein (MAG) Ab, IgM, EIA		

LAST EDITED: 2025-06-20 PAGE 15 OF 23



QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 06/18/2025 07:02 Received: 06/18/2025 07:02

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Myelin-Associated Glycoprotein (MAG) Ab, 1:1600 H <1:1600 titer QCRL

IgM, EIA

Reference ranges for MAG Ab (IgM) EIA:

Normal: <1:1600

Moderately Elevated: 1:1600-1:3200

Highly Elevated: >=1:6400

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics. It has not been cleared or approved by the FDA. This assay has been validated pursuant to the

CLIA regulations and is used for clinical purposes.

Test Performed at:

Quest Diagnostics Nichols Institute

33608 Ortega Highway

San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

**Reported Date:** 06/18/2025 07:02 MAGME

Performing Site:

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL,  $\,$  . - NOT TESTED

H418000001 WX0000003826 Printed D&T: 06/18/25 07:02 Ordered By: CLIENT CLIENT WX000000000002823



**JULY 2025** 

Inactivate Test With Replacement				
Effective Date	-	20/2025		
Name	Inactivated Test			
Name Code		BK Virus DNA PCR, Qualitative, Plasma		
Legacy Code		PBKQL KQUALP		
Interface Order Code		092790		
interface order code	Replacement Te			
Name	· · · · · · · · · · · · · · · · · · ·	CR, Qualitative, Pl	asma	
Code		BKQLP	asilia	
CPT Code(s)	87798	BRQLF		
Notes	New York DOH Approval Status: Yes			
Specimen Requiren				
Specimen Requirer	Collect: Lavender EDTA			
Specimen Required	Specimen Preparation: Centrifuge and separate plasma from cells within 8 hours of collection.  Send 2.0 mL plasma in a screw capped plastic vial. Dedicated specimens are required. Specimens used in other assays will not be tested.  Minimum Volume: 1.0 mL  Transport Temperature: Frozen			
Rejection Criteria	Serum, heparinized specimens, shared specimens, specimens submitted to repeated freeze-thaw cycles, specimens received in non-sterile or leaking containers, specimens that do not meet the storage/handling conditions criteria above.			
Stability	Room temperature: 1 day Refrigerated: 5 days Frozen (-20°C): 30 days Frozen (-70°C): 6 months			
<b>Performing Informa</b>	ation			
Methodology		hain Reaction (PC	CR)	
Reference Range	BKV QUAL: NO	T DET (Not detec	ted)	
Performed Days	Monday - Friday			
Turnaround Time	1 - 3 days			
Performing Laboratory	ry Warde Medical Laboratory			
Interface Informati	on			
Legacy Code		BKQLP		
Interface Order Code	3	000449		
Result Code	Name	LOINC Code	AOE/Prompt	
3000448	BK Virus DNA, Qualitative, Plasma		No	

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 36 Y

Molecular

Collected: 06/17/2025 14:48 Received: 06/17/2025 14:48

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

BK Virus DNA PCR, Qualitative, Plasma

BK Virus DNA, Qualitative, Plasma Not detected Not detected WMRL

This test utilizes the polymerase chain reaction to amplify sequences from the VP1 region of the BK virus genome. The qualitative limit of detection is  $100~\rm copies/mL$  2.00  $\log(10)~\rm copies/mL$ ) A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

**Reported Date:** 06/17/2025 14:48 BKQLP

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H417000002 WX0000003826 Printed D&T: 06/17/25 14:48 Ordered By: CLIENT CLIENT WX0000000000002823



**JULY 2025** 

Inactivate Test	With Replacement		
Effective Date	7/29/2025		
	Inactivated Test		
Name	BK Virus DNA PC	R, Quantitative, P	Plasma
Code		PBKQN	
Legacy Code	BK	QUANTP	
Interface Order Code	3	092740	
	Replacement Te	est	
Name	BK Virus DNA PC	R, Quantitative, P	Plasma
Code		BKQNP	
CPT Code(s)	87799		
Notes	New York DOH Approval Status: Yes		
Specimen Requiren	nents		
Specimen Required	Collect: Lavender EDTA  Specimen Preparation: Centrifuge and separate plasma from cells within 8 hours of collection.  Send 2.0 mL plasma in a screw capped plastic vial. Dedicated specimens are required. Specimens used in other assays will not be tested.  Minimum Volume: 1.0 mL  Transport Temperature: Frozen		
Rejection Criteria	Serum specimens, heparinized specimens, shared specimens, specimens submitted to repeated freeze-thaw cycles, specimens received in non-sterile or leaking containers.		
Stability	Room temperature: 1 day Refrigerated: 5 days Frozen (-20°C): 30 days Frozen (-70°C): 6 months		
Performing Informa	ation		
Methodology		Chain Reaction (Po	CR)
Reference Range	BKV	DET (Not detecte QUANT: <50 IU/r BKV: <1.7 log(10)	mL
Performed Days	Monday - Friday	<u> </u>	
Turnaround Time	1 - 3 days		
Performing Laboratory	Warde Me	Warde Medical Laboratory	
Interface Informati	on		
Legacy Code		BKQNP	
Interface Order Code	3	000454	
Result Code	Name	LOINC Code	AOE/Prompt
3000451	BK Virus DNA, Qualitative, Plasma	32362-6	No
3000452	BK Virus DNA, Quantitative, Plasma	32284-2	No
3000453	Log BK Virus DNA, Plasma	44805-0	No

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1968 56 Y

Molecular

Collected: 06/17/2025 14:52 Received: 06/17/2025 14:52

Test Name Result Flag Ref-Ranges Units Site

BK Virus DNA PCR, Quantitative, Plasma

BK Virus DNA, Qualitative, Plasma

Not detected

Not detected

Not detected

WMRL

BK Virus DNA, Quantitative, Plasma

<50

<50

IU/mL

WMRL

Log BK Virus DNA, Plasma

<1.70

<2.40

Log (10) IU/mL

WMRL

WMRL

This test utilizes a polymerase chain reaction to amplify sequences from the VP1 regions of the BK virus genome. Real-time detection and quantification are used to determine the viral copy number. The analytical measurement range is 125 to 5 million copies/mL (2.10 to 6.70  $\log(10)$  copies/mL). The qualitative limit of detection is 100  $\log(1.78 \log(10))$  copies/mL).

Specimens reported as "DETECTED" but <125 copies/mL contain detectable levels of BK virus DNA but the viral load is below the limit of quantitation. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

**Reported Date:** 06/17/2025 14:52 BKQNP

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H417000004 WX0000003827 Printed D&T: 06/17/25 14:52 Ordered By: KAJAL SITWALA, MD, PHD WX00000000002516



**JULY 2025** 

Inactivate Test With Replacement				
Effective Date		/29/2025		
	Inactivated Test			
Name		ology Consultatio	on	
Code		RBMA		
Legacy Code		RBMA		
Interface Order Code		3515295		
	Replacement To	est		
Name	Renal Pathology	Consultation, We	t Tissue	
Code		RPCWT		
CPT Code(s)	Variable - may include: 88305, 88313, 88346,	88348, 88350		
Notes	New York DOH Approval Status: Yes			
Specimen Requiren	nents			
Specimen Required	Collect: Kidney biopsy  Specimen Preparation: Please call Warde Medical Laboratory for special collection kit and collection instructions.  Minimum Volume: Entire specimen  Transport Temperature: See collection kit instructions			
Stability	See collection kit instructions			
Performing Informa				
Methodology	Light Microscopy Electro	Light Microscopy Electron Microscopy Immunohistology		
Reference Range		ee report		
Performed Days	Monday - Friday			
Turnaround Time	12 - 25 days			
Performing Laboratory	·	nic Laboratories		
Interface Informati	Interface Information			
Legacy Code	RPCWT			
Interface Order Code	3800402			
Result Code	Name	LOINC Code	AOE/Prompt	
3800403	Interpretation	60570-9	No	
3800404	Participated in the Interpretation		No	
3800406	Report electronically signed by	19139-5	No	
3800407	Addendum	35265-8	No	
3800408	Gross Description	22634-0	No	
3800409	Material Received	85298-8	No	
3800411	Disclaimer	62364-5	No	
3800412	Case Number	80398-1	No	

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 06/18/2025 07:08 Received: 06/18/2025 07:08

Test Name Result Flag Ref-Ranges Units Site

Renal Pathology Consultation, Wet Tissue

Interpretation SEE BELOW MMRL

FINAL DIAGNOSIS

Kidney, needle biopsy: 1) Diffuse sclerosing and membranous lupus nephritis, ISN/RPS class IV-G (C) and class V. 2) Amyloidosis, compatible with AA type, involving vessels and glomeruli. See comment.

Electron microscopy will be reported as an addendum.

#### COMMENT

The biopsy shows approximately 50% global glomerulosclerosis as well as segmental glomerular scars in additional glomeruli, compatible with diffuse sclerosing lupus nephritis. No lupus disease activity is identified in the sample. Immunofluorescence shows an immune complex glomerulonephritis, compatible with lupus nephritis. By light microscopy, glomerular basement membrane pinholes are seen on a silver stain, indicative of an additional component of membranous lupus nephritis. In addition, Congo red positive material si seen in the vessels and segmentally in the glomeruli; this material shows staining for serum amyloid A by immunohistochemistry, compatible with AA amyloidosis.

#### MICROSCOPIC DESCRIPTION

LIGHT MICROSCOPY: Tissue sections are cut and stained with HandE, PAS, Masson trichrome and Jones methenamine silver to aid in the morphological interpretation. Sections reveal renal cortex and contain approximately 20 glomeruli, 10 of which are globally sclerotic. The glomeruli show mild to moderate mesangial hypercellularity and mesangial matrix expansion. Approximately six glomeruli show segmental scars. Hyaline is present in segmental capillary loops. No endocapillary hypercellularity, karyorrhectic debris, necrotizing lesions or crescents, or wire loop lesions are identified. Numerous glomerular capillary loops show basement membrane pinholes on a silver stain. TUBULES AND INTERSTITIUM: Interstitial fibrosis with tubular atrophy affects approximately 40% of the sampled cortex. There is a focal sparse mononuclear inflammatory cell infiltrate in areas of interstitial fibrosis.

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H418000002 WX0000003826 Printed D&T: 06/18/25 07:08 Ordered By: CLIENT CLIENT WX000000000002823

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 3



QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108

#### **EXAMPLE, REPORT W**

WX0000003826 F 12/05/1988 36 Y

**Referral Testing** 

Collected: 06/18/2025 07:08 Received: 06/18/2025 07:08

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

VESSELS: Arterioles show moderate to severe intimal hyalinosis as well as medial thickening. Sampled small arteries show focal mild fibrous intimal thickening.

IMMUNOFLUORESCENT HISTOLOGY: Tissue submitted for immunofluorescence contains approximately seven glomeruli, four to five of which are globally sclerotic. The glomeruli show granular mesangial and capillary loop staining for IgG (2+), IgM (2+), C3 (3+), and kappa (2+) and lambda (2+) light chains. there is trace granular mesangial staining for C1q. The glomeruli are negative for IgA> tubular epithelial cell nuclei show staining for IgG (tissue ANA). There is focal granular interstitial and tubular basement membrane staining for IgG, IgG, C3, and kappa and lambda light chains. The glomeruli are negative for fibrinogen. Staining for albumin is unremarkable.

Participated in the Interpretation SEE BELOW MMRL

RESULT: Test, Interpretation

Report electronically signed by SEE BELOW MMRL

MONIQUE GARZA

I verify that I have examined all relevant slides/materials for the specimen(s) and rendered or confirmed the diagnosis.

Addendum . MMRL
Gross Description SEE BELOW . MMRL

Light Microscopy: Received in formalin for light microscopy: 1 piece(s) of tissue measuring  $0.5 \times 0.5$  cm. Submitted in total in block(s) A1. (GEJ)

Electron Microscopy: Received in glutaraldehyde/Trumps for electron microscopy: 1 piece(s) of tissue measuring 0.2 x 0.1 cm. (GEJ)

Immunofluorescence: Received in Zeus for

immunofluorescence: 1 piece(s) of tissue measuring  $0.5 \times 0.7$  cm. Submitted in total for immunofluorescence. (GEJ)

Material Received SEE BELOW MMRL

1 - Formalin 10% wet tissue

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL,  $\,$  . - NOT TESTED

H418000002 WX0000003826 Printed D&T: 06/18/25 07:08 Ordered By: CLIENT CLIENT WX000000000002823

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 2 OF 3



QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003826 F 12/05/1988 36 Y

**Referral Testing** 

Collected: 06/18/2025 07:08 Received: 06/18/2025 07:08

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

1 - Zeus wet tissue

1 - Gluta/Trumps wet tissue

Disclaimer SEE BELOW MMRL

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements.

This test has not been cleared or approved by the U.S. Food

This test has not been cleared or approved by the U.S. Food

and Drug Administration.

Case Number KR-25-57 MMRL

Test Performed by:
Mayo Clinic Laboratories - Rochester Main Campus
200 First Street SW, Rochester, MN 55905
Lab Director: Nikola A. Baumann Ph.D.; CLIA# 24D0404292

**Reported Date:** 06/18/2025 07:08 RPCWT

Performing Site

MMRL: MAYO MEDICAL REFERENCE LAB 3050 Superior Drive NW Rochester MN 55901

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H418000002 WX0000003826 Printed D&T: 06/18/25 07:08 Ordered By: CLIENT CLIENT WX000000000002823

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 3 OF 3



**JULY 2025** 

Inactivate Test	With Replacement		
Effective Date	-	7/29/2025	
	Inactivated Test		
Name	Free Testosterone		
Code		TESF	
Legacy Code		TESF	
Interface Order Code		1000822	
	Replacement 1	est	
Name	Testosterone, Free	e, Bioavailable and	l Total, MS
Code		TESB	
CPT Code(s)	84403, 84270, 82040		
Notes	New York DOH Approval Status: No		
	NOTE: This is an existing test offered at Wa	rde Medical Labo	ratory.
Specimen Requiren	nents		
Specimen Required	Collect: Red top  Specimen Preparation: Centrifuge, separate serum from cells and send 3.0 mL serum in a screw capped plastic vial.  Minimum Volume: 2.0 mL  Transport Temperature: Refrigerated		
Rejection Criteria	Samples other than serum from plain red top collection tubes, serum separator tubes (SST), plasma samples, lipemic samples, hemolyzed samples, and samples received past stability.		
Stability	Room temperature: 8 hours Refrigerated: 7 days Frozen: 2 months		
Performing Informa	ation		
Methodology	Liquid Chromatography - Tandem Mass Spectrometry (LC/MS/MS), Calculation, Nephelometry, Immunochemiluminescent Assay		
Reference Range		See report	
Performed Days			
Turnaround Time	3 - 6 days		
Performing Laboratory		1edical Laborator	У
Interface Informati	on		
Legacy Code		TESB	
Interface Order Code		3000403	
Result Code	Name	LOINC Code	AOE/Prompt
3000169	Testosterone, Total, LC/MS/MS	2986-8	No
3000404	Testosterone, Free		No
3000406	Testosterone, Bioavail		No
3000391	Sex Hormone Binding Globulin	13967-5	No
3000407	Albumin	1751-7	No

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1968 56 Y

**Immunochemistry** 

Collected: 03/11/2025 07:58 Received: 03/11/2025 07:58

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Testosterone, Free, Bioavailable and Total, MS

Testosterone, Total, LC/MS/MS 300 250 - 1100 ng/dL WMRL

This test was developed and its performance characteristics determined by Warde Medical Laboratory in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration. This test is used for patient testing purposes. It should not be

regarded as investigational or for research.

Testosterone, Free 70.6 46.0 - 224.0 pg/mL WMRL

Free and bioavailable testosterone are calculated from measured values of total testosterone, albumin, and SHBG. Total testosterone is measured by liquid chromatographymass spectrometry (LC-MS/MS); albumin and SHBG are measured by

 $\verb|immunoassay|.$ 

Testosterone, Bioavail 129.9 110.0 - 575.0 ng/dL WMRL Sex Hormone Binding Globulin 15 13 - 90 nmol/L WMRL Albumin 4.0 3.5 - 5.2 g/dL WMRL

Reported Date: 03/11/2025

08:00 TESB

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL,  $\,$  . - NOT TESTED

H111000000 WX0000003827 Printed D&T: 03/11/25 08:00 Ordered By: KAJAL SITWALA, MD, PHD WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**JULY 2025** 

	sadd a l			
	With Replacement			
Effective Date		29/2025		
Inactivated Test				
Name	BK Virus DNA P	CR, Qualitative, U	Jrine	
Code	l	UBKQL		
Legacy Code	Вн	(QUALU		
Interface Order Code	31	092780		
	Replacement Te	est		
Name	BK Virus DNA P	CR, Qualitative, U	Jrine	
Code	[	BKQLU		
CPT Code(s)	87798			
Notes	New York DOH Approval Status: Yes			
Specimen Requiren	nents			
Specimen Required	Collect: Random urine  Specimen Preparation: Collect neat urine in a screw capped plastic container. Thoroughly mix urine by inverting or vortexing the collection cup immediately prior to transfer into the Alinity Urine Transport Tube. Use the plastic transfer pipette to transfer the urine until the liquid level falls within the fill window on the tube label. Urine must be transferred within 24 hours of collection.  Minimum volume: 2.4 mL  Transport Temperature: Refrigerated			
Rejection Criteria	Under- or over-filled tubes, urine specimens that have exceeded the 24-hour stability.			
Stability	Neat Urine: Room temperature: 24 hours Refrigerated: 24 hours Frozen: Unacceptable  Stabilized Urine: Room temperature: 90 days Refrigerated: 90 days Frozen: Unacceptable		,	
<b>Performing Informa</b>	ation			
Methodology		hain Reaction (PC	CR)	
Reference Range	BKV QUAL: NOT DET (Not detected)			
Performed Days	Monday - Friday			
Turnaround Time	1 - 3 days			
Performing Laboratory	Warde Medical Laboratory			
Interface Informati				
Legacy Code	Ī	BKQLU		
Interface Order Code	31	000447		
Result Code	Name	LOINC Code	AOE/Prompt	
3000446	BK Virus DNA, Qualitative, Urine	47251-4	No	

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1968 56 Y

Molecular

Collected: 06/17/2025 14:50 Received: 06/17/2025 14:50

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

**BK Virus DNA PCR, Qualitative, Urine** 

BK Virus DNA, Qualitative, Urine DETECTED AB Not detected WMRL

This test utilizes the polymerase chain reaction to amplify sequences from the VP1 region of the BK virus genome. The qualitative limit of detection is  $100~\rm copies/mL$  2.00  $\log(10)~\rm copies/mL$ ) A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.

**Reported Date:** 06/17/2025 14:50 BKQLU

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

H417000003 WX0000003827 Printed D&T: 06/17/25 14:50 Ordered By: KAJAL SITWALA, MD, PHD WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**JULY 2025** 

<b>Inactivate Test</b>	With Replacement		
Effective Date	-	9/2025	
Inactivated Test			
Name	BK Virus DNA PCR, Quantitative, Urine		
Code		BKQN	· · · · · · · · · · · · · · · · · · ·
Legacy Code		QUANTU	
Interface Order Code		92700	
	Replacement Tes	st	
Name	BK Virus DNA PCF	R, Quantitative,	Urine
Code		KQNU	
CPT Code(s)	87799		
Notes	New York DOH Approval Status: Yes		
Specimen Requirer	nents		
Specimen Required	Collect: Random urine  Specimen Preparation: Collect neat urine in a screw capped plastic container. Thoroughly mix urine by inverting or vortexing the collection cup immediately prior to transfer into the Alinity Urine Transport Tube. Use the plastic transfer pipette to transfer the urine until the liquid level falls within the fill window on the tube label. Urine must be transferred within 24 hours of collection.  Minimum Volume: 2.4 mL  Transport Temperature: Refrigerated		
Rejection Criteria	Under- or over-filled tubes, urine specimens that	at have exceede	ed the 24-hour stability.
Stability	Neat Urine: Room Temperature: 24 hours Refrigerated: 24 hours Frozen: Unacceptable  Stabilized Urine: Room temperature: 90 days Refrigerated: 90 days Frozen: Unacceptable		,
Performing Informa	ation		
Methodology		ain Reaction (Po	CR)
Reference Range	BKV QUAL: NOT DET (Not detected)  BKV QUANT: <50 IU/mL  Log BKV: <1.7 log (10) IU/mL		
Performed Days	Monday - Friday	,	
Turnaround Time	1 - 3 days		
Performing Laboratory	Warde Med	dical Laboratory	
Interface Informati	on		
Legacy Code	В	KQNU	
Interface Order Code	30	00444	
Result Code	Name	LOINC Code	AOE/Prompt
3000441	BK Virus DNA, Qualitative, Urine	33978-8	No

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**JULY 2025** 

3000442	BK Virus DNA, Quantitative, Urine	32285-9	No
3000443	Log BK Virus DNA, Urine	43201-3	No

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QC ACCOUNT (WARDE) 300 W. TEXTILE ANN ARBOR MI 48108 **EXAMPLE, REPORT W** 

WX0000003827 M 07/08/1968 56 Y

Molecular

Collected: 06/17/2025 15:23 Received: 06/17/2025 15:23

Test Name Result Flag Ref-Ranges Units Site

**BK Virus DNA PCR, Quantitative, Urine** 

WMRL BK Virus DNA. Qualitative. Urine **DETECTED** Not detected AB <50 WMRL BK Virus DNA, Quantitative, Urine 500 IU/mL н WMRL Log BK Virus DNA, Urine 2.70 <2.40 Н Log (10) IU/mL

This test utilizes a polymerase chain reaction to amplify sequences from the VP1 regions of the BK virus genome. Real-time detection and quantification are used to determine the viral copy number. The analytical measurement range is 125 to 5 million copies/mL (2.10 to 6.70  $\log(10)$  copies/mL). Specimens with viral loads greater than 5 million copies/mL are diluted to establish the endpoint. The qualitative limit of detection is  $100 \; \text{copies/mL}(1.78 \; \log(10) \; \text{copies/mL})$ .

Specimens reported as "DETECTED" but <125 copies/mL contain detectable levels of BK virus DNA but the viral load is below the limit of quantitation. A "Not detected" result does not rule out infection.

This test uses commercial reagents that have not been approved or cleared by the FDA. The FDA has determined that such clearance or approval is not necessary. The performance characteristics of this procedure were determined by Warde Medical Laboratory.

This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.  $\,\,$ 

Reported Date: 06/17/2025 15:23 BKQNU

Performing Site:

WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL,  $\,$  . - NOT TESTED

H417000005 WX0000003827 Printed D&T: 06/17/25 15:24 Ordered By: KAJAL SITWALA, MD, PHD WX00000000002516

Kajal V. Sitwala, MD, PhD - Medical Director Form: MM RL1 PAGE 1 OF 1



**JULY 2025** 

Inactivate Test Without Replacement	
Effective Date	7/21/2025
Name	HLA B-27 Genotyping (Confirmation)
Code	B27A
Legacy Code	HLAB27A
Interface Code	3511330
Notes	Test discontinued.

Inactivate Test Without Replacement	
Effective Date	7/21/2025
Name	Lactic Acid, Plasma
Code	LACPL
Legacy Code	LACPL
Interface Code	3600036
Notes	Test discontinued.

Inactivate Test Without Replacement		
Effective Date	7/21/2025	
Name	ThinPrep with reflex to HPV High Risk E6/E7	
Code	TPRHH	
Legacy Code	TPRHH	
Interface Code	3600039	
Notes	Test discontinued.	

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